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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,348	06/14/2002	Max Gregor Paping	702-011892	3813

7590 12/16/2003

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EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,348

Applicant(s)

PAPING ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-51 is/are pending in the application.
- 4a) Of the above claim(s) 47-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

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Applicant's election the claims 36-46 of Group I (Paper # 8), is acknowledged.

Claims 47-51 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Claims 36-46 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-46 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The term "an amount" in claim 1 is a relative term, which renders the claims indefinite. The term "an amount" does not define the amount of starch in the rubber latex, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(B) The terms "incorporating" or "incorporated" in claims 36-38 are relative terms, which renders the claims indefinite. The terms "incorporating" or "incorporated" do not define how the starch is incorporated into the latex, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(C) Regarding claims 37 and 38, the phrase "such that" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

(D) Claim 41, sets-forth improper Markush terminology. The language "starch is " should be changed to --starch is selected from the group consisting of--.

³
Claim which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dove (U.S. Patent 5,691,446).

The applicants' claims are directed toward rubber latex having reduced allergen activity obtained by the method of claim 36. Additional claim limitations include the rubber latex articles surgical glove, condom and inflatable balloon.

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Dove discloses the reduced allergenicity natural rubber latex articles (see abstract).

Dove discloses a method for producing "hypo" or reduced allergenic natural rubber latex articles (col. 4, lines 27-46). Dove also discloses the production of rubber latex articles such as gloves, inflatable balloons and condoms (col. 7, lines 14-22 and col. 8, lines 36-37). Therefore Dove's rubber latex articles are encompassed by the applicants' claims.

Claims 42-46 are drawn to the rubber latex articles having reduced allergen activity. How the said rubber latex articles are prepared is not given patentable weight. Claims 42-46 are product by process claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockum (4,143,109) in view of Fitt et al. (U.S. Patent 5,385,608).

Claims 36-41 are drawn to the method for reducing the allergen activity of rubber latex comprising incorporating an amount of starch in the rubber latex. Additional claim limitations include the allergen activity of said rubber latex is maximally 20% and 50%, of the allergen activity of rubber latex without starch; starch is modified by gelatinizing the starch and subsequently crosslinking the starch with glyoxal; the allergen activity of rubber latex containing modified starch is maximally 5%, 15% and 40%.

Stockum teaches a method for producing rubber latex in combination with starch (abstract). Stockum discloses the natural rubber latex in combination with an epichlorohydrin cross-linked corn starch (col. 4, lines 22-26) and its use in medical glove and other articles (col. 4, lines 41-43). Stockum also discloses a method wherein a part of fluid latex is mixed with cross-linked corn starch and used to cover a preformed latex gloves (col. 4 and 5, Example 1). Stockum differs from the applicant's invention in that Stockum does not provide an explicit example of modified starch with reduced allergenic activity.

Fitt et al. teach a method for producing modified starch with reduced allergenic activity (col.2, lines 65-68 thru col.3; lines 1-6). Fitt et al disclose the starch from various cereal and root materials including corn, waxy corn, potato and tapioca (col. 4, lines 9-13). Fitt et al. disclose the gelation and crosslinking reaction of starch with phosphorus oxychloride in col. 6, lines 42-60. Fitt et al. also disclose that the said modified starch

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can be used in surgical gloves (col. 7, lines 44-47). The prior art (Fitt et al.) is silent about the percentage reduction of allergenic activity in the modified starch, therefore one skilled in the art would assume the allergenic activity in the modified starch do not exceed numbers (percentage) set forth in applicants claims.

Therefore, one of ordinary skill in the art would have found the applicants claimed method for producing rubber latex in combination with a modified starch or starch, to have been obvious at the time the invention was made having the above-cited references before him. Since Stockum teaches a method for producing rubber latex in combination with the cross-linked starch and Fitt et al. teach a method for producing modified starch with reduced allergenic activity, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a rubber latex comprising an amount of starch or modified starch. Stockum provides the motivation to produce a "powderless glove" for surgery, thus avoiding allergen activity caused by powdery starch in a rubber latex glove (col.1, lines 45-51).

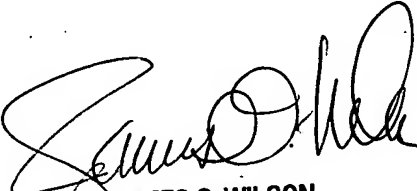
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
December 12,2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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